PCT/EP2003/006851

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 30A-91 480	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/006851	International filing date (*day/month/year*) 27 June 2003 (27.06.2003)	Priority date (*day/month/year*) 01 July 2002 (01.07.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/48		
Applicant WANK, Rudolf		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 23 January 2004 (23.01.2004)	Date of completion of this report 28 October 2004 (28.10.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/006851

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☒ the description:

pages 1-8, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages 1-16, filed with the letter of 30 July 2004 (30.07.2004)

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1, 2, 4-16

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☒ the claims, or said claims Nos. 1, 2, 4-16 are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1, 2, 4-16 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The subject matter of claims 1, 2 and 4-16 was only partially searched (see extra sheet PCT/ISA/210 in the international search report) because of insufficient disclosure and support by the description (PCT Articles 5 and 6).

The applicant is advised that claims or parts of claims relating to inventions in respect of which no international search report has been established cannot normally be the subject of an international preliminary examination (PCT Rule 66.1(e)). In its capacity as International Preliminary Examining Authority the EPO generally will not carry out a preliminary examination for subjects that have not been searched. This also applies to cases where the claims were amended after receipt of the international search report (PCT Article 19) or where the applicant submits new claims in the course of the procedure under PCT Chapter II.

The functional definition "dopamine receptor agonists" (claim 1) is not supported over its entire scope (PCT Articles 5 and 6) because the applicant shows the claimed therapeutic effect only for bromocriptine.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-16	YES
	Claims		NO
Inventive step (IS)	Claims	6	YES
	Claims	1-5, 7-16	NO
Industrial applicability (IA)	Claims	1-16 (see supplemental sheet)	YES
	Claims		NO

2. Citations and explanations

This report makes reference to the following documents:

D1: WO 99/47133 A (RESNICK MARK G; SOMERSET PHARMACEUTICALS INC (US)), 23 September 1999 (1999-09-23)

D2: US-A-5 792 748 (MEIER ALBERT H ET AL), 11 August 1998 (1998-08-11)

D3: US 2001/049350 A1 (CINCOTTA LOUIS ET AL), 6 December 2001 (2001-12-06)

Novelty - PCT Article 33(2)

WO 99/47133 (D1) shows selegiline-containing preparations for the topical treatment of wounds, burns and photodamaged skin. The subject matter of independent claim 1 is novel over D1 because D1 does not mention the therapy of skin tumours and warts.

US 579 2748 (D2) discloses the inhibition of neoplasia, including melanomas (see the claims), by modulation of the prolactin level. Bromocriptine can be used with an increased prolactin level. Bromocriptine is systemically administered.

US 2001/049350 (D3) describes the use of bromocriptine for

the photodynamic therapy of tumours, for example in the case of skin cancer. Bromocriptine is systemically used.

Since D2 and D3 disclose only the systemic administration of bromocriptine, the subject matter of independent claim 1 is novel over the disclosure of D2 and D3.

Inventive step - PCT Article 33(3)

Document D2 should be regarded as the closest prior art. In that document, neoplasia, including melanomas, is systemically treated with bromocriptine. However, it would be obvious for a person skilled in the art to administer bromocriptine topically to skin tumours, especially since the topical administration of dopamine receptor agonists in the case of skin diseases is already known (D1).

The subject matter of the dependent claims appears to relate only to well known alternatives. For this reason, an inventive step cannot at present be acknowledged in the subject matter of claims 1-5 and 7-16.

Documents D1-D3 do not contain any indication of the topical treatment of warts with bromocriptine.

Industrial applicability - PCT Article 33(4)

In the PCT Contracting States, there are no uniform criteria for assessing the industrial applicability of Claims 1-16 in their present form. Patentability can also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the use of a compound in a medical treatment; it does, however, allow claims to the first use of a known compound in a medical treatment or to the use of such a compound in the manufacture of a drug for a new medical treatment.